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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Reporting on Health Care Quality and Patient Safety

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Availability – New Common Formats.

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development of sets of common definitions and reporting formats (Common Formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the release of the Common Formats – Community Pharmacy Version 1.0.

DATES: Ongoing public input.

ADDRESSES: The Common Formats – Community Pharmacy Version 1.0 and the remaining Common Formats can be accessed electronically at the following HHS Web site: <http://www.pso.ahrq.gov/common/>.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Choo, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N100B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

[Background](#)

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR Part 3 (Patient Safety Rule), published in the Federal Register on November 21, 2008, 73 FR 70732-70814, provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The collection of patient safety work product allows the aggregation of data that help to identify and address underlying causal factors of patient safety and quality issues.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other health care providers may assemble information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs – called “patient safety work product” – is privileged and confidential. Patient safety work product is used to conduct patient safety activities, which may include identifying events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Act and Patient Safety Rule which can be accessed electronically at: <http://www.pso.ahrq.gov/legislation/>.

Definition of Common Formats

The term "Common Formats" refers to the common definitions and reporting formats, specified by AHRQ, that allow health care providers to collect and submit standardized information regarding patient quality and safety to PSOs and other entities. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system; rather the formats are intended to enhance the ability of health care providers to report information that is standardized both clinically and electronically.

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF), and the public, AHRQ has developed Common Formats for three settings of care — acute care hospitals, skilled nursing facilities, and community pharmacies — in order to facilitate standardized data collection and analysis. The scope of Common Formats applies to all patient safety concerns including: incidents – patient safety events that reached the patient, whether or not there was harm; near misses or close calls – patient safety events that did not reach the patient; and unsafe conditions – circumstances that increase the probability of a patient safety event.

AHRQ's Common Formats for patient safety event reporting include:

- Event descriptions (definitions of patient safety events, near misses, and unsafe conditions to be reported);
- Specifications for patient safety aggregate reports that derive from event descriptions;
- Delineation of data elements and algorithms to be used for collection of adverse event data to populate the reports; and
- Technical specifications for electronic data collection and reporting.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning. They also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be

submitted electronically to the PSO Privacy Protection Center (PPC) for data de-identification and transmission to the Network of Patient Safety Databases.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provided an evidence base to inform construction of the Common Formats. The inventory included many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (e.g., from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems were included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has convened the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS – CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration – as well as the DoD and VA.

Since the initial release of the Common Formats in August 2008, AHRQ has regularly revised the formats based upon public comment. First, AHRQ reviews existing patient safety practices and event reporting systems. Then, AHRQ works in collaboration with the PSWG and Federal subject matter experts to develop and draft the Common Formats. In addition, the PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. Next, AHRQ solicits feedback from private sector

organizations and individuals. Finally, based upon the feedback received, AHRQ further revises the Common Formats.

Participation by the private sector in the development and subsequent revision of the Common Formats is achieved through working with the NQF. The Agency engages the NQF, a non-profit organization focused on health care quality, to solicit comments and advice regarding proposed versions of the Common Formats. AHRQ began this process with the NQF in 2008, receiving feedback on AHRQ's 0.1 Beta release of the Common Formats for Event Reporting – Hospital. After receiving public comment, the NQF solicits the review and advice of its Common Formats Expert Panel and subsequently provides feedback to AHRQ. The Agency then revises and refines the Common Formats and issues them as a production version. AHRQ has continued to employ this process for all subsequent versions of the Common Formats.

In 2014, representatives from U.S. community pharmacies approached AHRQ regarding collaboration to develop Common Formats for the community pharmacy setting. Development of the new Formats began using the existing AHRQ Common Formats Medication module from the AHRQ Common Formats for Event Reporting – Hospital, Version 1.2, as a starting point. AHRQ, in conjunction with community pharmacy representatives, designed these new formats to facilitate improved detection and understanding of medication-related events originating in pharmacies. If implemented as specified, the Common Formats – Community Pharmacy Version 1.0 will allow aggregation of medication-related data across different pharmacy providers.

On October 6, 2015, AHRQ announced the availability of the – Common Formats Retail Pharmacy Version 0.1 Beta – for review and comment in the Federal Register (80 FR 60385-60387). After obtaining feedback from both the private and public sectors, the Agency finalized the format and renamed it Common Formats – Community Pharmacy Version 1.0. All elements - including the event description, aggregate reports, data elements and algorithms, and technical specifications - will be posted at the PSOPPC Web site: https://www.psoppc.org/psoppc_web

More information on the Common Formats can be obtained through AHRQ's PSO Web site: <http://www.pso.ahrq.gov/>.

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